K082974

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DENTSPLY

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510(k) SUMMARY

CONTACT: Helen Lewis

DATE PREPARED: October 2, 2008

TRADE OR PROPRIETARY NAME: Mystique MB Ceramic Brackets

CLASSIFICATION NAME:	Orthodontic Ceramic Brackets	872.5470
PREDICATE DEVICES:	Orthodontic Ceramic Brackets	K042178

DEVICE DESCRIPTION: The Orthodontic Ceramic Bracket is in commercial distribution and consists of a chemically treated base. The modification to the Orthodontic Ceramic Bracket consists of a mechanical lock base and the brackets are referred to as the Mystique MB Ceramic Brackets. Mystique MB Ceramic Brackets are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire, to alter the tooth position. The mechanical lock base includes rhomboid and "torque-in-the-base" features. The bracket is transparent and has indented walls and is available with or without glass coating in the wire slot.

INTENDED USE: Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

TECHNOLOGICAL CHARACTERISTICS: The Mystique MB Ceramic Brackets represent a minor design modification to K042178. There are no changes in intended use or fundamental scientific technology.

All of the components found in Mystique MB Ceramic Brackets have been used in legally marketed devices and/or were found safe for dental use. Mystique MB Ceramic Brackets are the same composition as the predicate device. Therefore, further biocompatibility testing is not necessary.

We believe that the prior use of the components of Mystique MB Ceramic Brackets in the legally marketed devices, the performance data provided, and previously submitted biocompatibility data support the safety and effectiveness of Mystique MB Ceramic Brackets for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

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Re: K082974
Trade/Device Name: Mystique MB Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: October 2, 2008
Received: October 9, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D FOR DR. CHIU LIN
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082974

Device Name: Mystique MB Ceramic Brackets

Indications for Use:

Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

These are the same indications for use previously cleared for K042178.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082974